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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/643,270	08/19/2003	Peter Zahner	4070		
75	90 05/26/2005		EXAMINER		
Peter Zahner			MCCORMICK EWO	MCCORMICK EWOLDT, SUSAN BETH	
Suite 203 27725 Old 41 R	toad		ART UNIT	PAPER NUMBER	
Bonita Springs,					
			DATE MAILED: 05/26/200	DATE MAILED: 05/26/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
Office Action Summany		10/643,270	ZAHNER, PETER			
	Office Action Summary	Examiner	Art Unit			
		Susan B. McCormick-Ewoldt	1654			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠	Responsive to communication(s) filed on <u>21 March 2005</u> .					
2a)⊠	This action is <b>FINAL</b> . 2b) ☐ This action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Dispositi	Disposition of Claims					
4)⊠ Claim(s) <u>1-23</u> is/are pending in the application.						
•	4a) Of the above claim(s) <u>16-23</u> is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
	)⊠ Claim(s) <u>1-15</u> is/are rejected.					
	Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority u	ınder 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
<ol> <li>Certified copies of the priority documents have been received.</li> </ol>						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.						
Oce the attached detailed Office action for a list of the certified topies not received.						
Attachmen	tie)					
_	e of References Cited (PTO-892)	4) Interview Summary	(PTO-413)			
2) Notic	e of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date  5) Notice of Informal Patent Application (PTO-152)				
	nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date	6) Other:	atom Application (F+O+192)			
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#### **DETAILED ACTION**

The amendment of March 21, 2005 is hereby acknowledged and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

## Claims Pending

Claims 16-23 are withdrawn from consideration and the withdrawal was made with traverse. Claims 1-15 are examined on the merits.

# Claim Rejections - 35 USC § 112

Claims 1, 7-8 and 10 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention for the reasons set forth in the previous Office action.

Claim 1 (a) remains unclear in its meaning of "Bio-Melanin extract." Applicant indicates that this is a specific product that is commercially available. However, Applicant has not defined exactly what is in this product. Thus it is unclear what compositions are encompassed by "Bio-Melanin."

Claims 1 and 10 remain rendered vague and indefinite by the terms "synergistically" and "synergistic" because the instant specification does not adequately disclose amounts and/or proportions of the claimed ingredients necessary to provide such a synergistic effect- i.e., the metes and bounds of this term are not clearly delineated because the instant specification fails to adequately teach synergistic amounts/proportions thereof (please note that synergism is well known in the art to be an unpredictable phenomenon highly dependent upon specific amounts and/or proportions of active ingredients therein). Applicant has not provided any argument to overcome this rejection.

Claims 7 and 8 recites the limitation "extract" in line 2. There is insufficient antecedent basis for this limitation in the claim because claim 6 states a "component". Applicant has not provided any argument to overcome this rejection.

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## Claim Rejections - 35 USC § 103

Claims 1-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over de Rigal et al. (US 5,618,521) in view of McCook et al. (US 5,306,486) and Pawelek et al. (US 5,618,519) for the reasons set forth in the previous Office action.

de Rigal *et al.* expressly teach using a composition for suitably for screening UVA and/or UVB irradiation containing titanium dioxide and zinc oxide, which are metal oxide nanopigments at a concentration from 1-10% (column 3, lines 23-30, 55-60; column 4, lines 8-12 and claims 9, 16-17). In addition, de Rigal *et al.* disclose using green tea extract in the concentration between 0.1 to 2% by weight (column 2, lines 41-49; column 3, line 1 and claim 5). de Rigal *et al.* does not teach using Bio melanin in the composition. Applicant's arguments filed March 21, 2005 have been fully considered but they are not persuasive.

Applicant argues that de Rigel *et al.* teach green tea concentration between 0.1 to 2% by weight and Applicant has a concentration of green tea at 6% by weight. One of ordinary skill in the art would expect to use more of an active ingredient in optimizing the workable ranges or concentrations of the component that would be beneficial.

McCook *et al.* disclose using green tea extract in a concentration ranging from 0.01 to 10% by weight and a sunscreen compound to inhibit UV absorption such as titanium dioxide or zinc oxide with the concentration ranging from 00.1 to 25% (column 2, lines 45-46, 60-61, 65-66; column 3, lines 1-2, 58-60 and claims 1-5).

Pawelek *et al.* disclose a composition that includes melanins to be used in a sunscreen (column 2, lines 35-37) and sources where melanin can be prepared (column 8, lines 39-41). In addition, Pawelek *et al.* teach that sun-screening agents can be added to the composition (column 7, lines 46-49). Applicant's arguments filed March 21, 2005 have been fully considered but they are not persuasive.

Applicant argues that in Pawelek et al., column 2, lines 35-37, does not point to any composition that includes melanin. This is not persuasive as Pawelek states "It is another object of the present invention to provide composition and methods for applying such melanins to mammalian skin and hair to provide a sun-screen." (emphasis added).

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Applicant argues that there is no disclosure or suggestion that the melanin may be combined with metal oxides or green tea. This is not persuasive as Applicant is directed to column 7, lines 46-48 which states "....if desired, the composition according to this embodiment comprises at least one additive selected from the group consisting of.....sunscreening agents...."

Thus, the melanin composition can include well-known sunscreens such as metal oxides (titanium dioxide and zinc oxide).

Although McCook et al. and de Rigal et al. disclose using green tea extracts from 0.01 to 10% by weight and .1 to 2%, respectively, it was obvious to one skilled in the art to increase the amount of green tea extract hence, the greater amount of polyphenols (i.e. antioxidant) in the composition.

One of ordinary skill in the art would have been motivated to combine de Rigal et al. with McCook et al. and Pawelek et al. because de Rigal et al. with McCook et al., both taught using green tea extract and titanium dioxide or zinc oxide for a composition that can be used as a sunscreen and Pawelek et al. taught that melanin used in a sunscreen compositions was advantageous. It is known in the art that titanium dioxide and zinc oxide provides photoprotective activity as stated in de Rigal et al. (column 3, line 55-60) and the amount of constituents claimed would be obvious in the claimed composition. Polyphenols are known in the art as an antioxidant which are an intrinsic characteristic of green tea which Camellia oleifera and Camellia sinensis.

Applicant argues there is no teaching to combine the melanin, green tea and titanium dioxide or zinc oxide with the references. In response to Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, these references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions that are used for sunscreen. It is well known that it is *prima facie* obvious to combine two or more ingredients

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each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re* Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re* Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re* Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in compositions to be used for sunscreen, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to be used for sunscreen. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re* Sussman, 1943 C.D. 518; *In re* Huellmantel 139 USPQ 496; *In re* Crockett 126 USPQ 186.

It would clearly have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use a composition made up of green tea extract, a UV ray blocking mineral pigment and melanin in an effective amount for a sunscreen composition, based upon the beneficial teaching provided by the cited references, as discussed above.

Therefore, the rejection is maintained and deemed final.

#### Summary

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

#### Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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